

REMARKS

The present Office Action addresses claims 1-12 and 14-22, rejecting claims 8, 9, 11, 12, 15, 16, and 20-22 as being anticipated by the prior art. Claims 1-7 and 17-19 are also objected to as being dependent upon a rejected base claim, and claim 14 is rejected as failing to satisfy 35 U.S.C. §112, second paragraph. By this amendment, claims 10, 14, 17-19, and 21 are amended. In particular, claim 10 is amended to change its dependency to claim 9, thereby providing proper antecedent basis for the claim limitations. Claim 14 is amended to change its dependency to claim 16, thereby providing proper antecedent basis to the claim limitations. Claim 17 is amended to reword and thereby clarify the claim language by reciting that the centralized vertical extension has a trapezoidal, circular or curved shape. Claims 18 and 19 are now amended to depend directly from independent claim 21. And, claim 21 is amended to recite "a" device, in order to provide proper antecedent basis for the claim limitations, and to correct the misspelling of the word "existing." In addition, Applicants also amend the specification at paragraph no. [001] to update the domestic priority data. Accordingly, no new matter is added by these amendments.

Applicants respectfully request reconsideration and withdrawal of all of the pending rejections in view of the amendments and the following remarks.

Claim Objections

In the Office Action, the Examiner objects to claim 17 as containing the grammatically awkward phrase "a shape selected from the group consisting of a trapezoid, circular and curved." Claim 17 is hereby amended to remove the confusing

phraseology and instead recite that the centralized vertical extension has a trapezoidal, circular or curved shape. The Examiner also objects to claim 21 as reciting "the therapeutic or prophylactic device" in the preamble, since claim 21 is independent. As helpfully suggested by the Examiner, Applicants amend claim 21 to recite "**a** therapeutic or prophylactic device" to correct the antecedent basis problem. Accordingly, Applicants believe that these amendments overcome the Examiner's objections to the claims. The Examiner is respectfully requested to reconsider and withdraw these objections.

Claim Rejections under 35 U.S.C. §112

The Examiner rejects claims 10 and 14 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. In particular, claim 10 is rejected for failing to provide proper antecedent basis for the claim limitation "said internal cavity," while claim 14 is rejected for failing to provide proper antecedent basis for the claim limitation "said biocompatible fluid." As helpfully suggested by the Examiner, Applicants amend claim 10 to depend from claim 9, while claim 14 is amended to depend from claim 16. Applicants believe that each of the Examiner's rejections are overcome by these amendments. Thus, the Examiner is kindly asked to reconsider and withdraw these rejections.

Prior Art Rejections Under 35 U.S.C. §102

The Examiner rejects claims 8-12, 15, 16, and 20-22 under 35 U.S.C. §102(b) as being anticipated by Kuslich (U.S. Patent No. 5,571,189). Claims 20-22 are additionally rejected under 35 U.S.C. §102(e) as being anticipated firstly by Ferree (U.S. Patent No. 6,245,107), and secondly by Bao et al. (U.S. Patent No. 6,224,630). For all of the following reasons, Applicants respectfully request reconsideration and withdrawal of each of these rejections.

The Kuslich Patent Does Not Anticipate the Claimed Invention

In the Office Action, the Examiner asserts that claims 8-12, 15, 16, and 20-22 are anticipated by Kuslich (U.S. Patent No. 5,571,189) under 35 U.S.C. §102(b). Applicants respectfully disagree with the Examiner's assertions that Kuslich anticipates the claimed invention.

First, it should be emphasized that Kuslich does not disclose or suggest a device for treating a spinal disc annulus having an aperture, as is claimed by Applicants. In fact, Kuslich does not teach anywhere in his specification that the implant device (40) referenced in the present Office Action is ever used to treat or repair an aperture in the annulus. In the Office Action, the Examiner asserts that the equatorial band (42) of device (40) opposes the annular wall and therefore inherently provides a platform for a traverse of fibroblasts or other normal cells of repair existing in and around the various layers of the disc annulus, since the band (42) can be made up of multiple layers of fabric that form the device. However, this is simply not the case with the Kuslich device.

In order to insert his expandable bag device (40) into the intervertebral disc space between vertebral bodies (12, 14), Kuslich bores an entrance (46) extending from the outer annulus fibrosus through the nucleus and then cuts a hollow chamber (44) in the intervertebral disc space and the adjacent vertebral bodies. By doing so, Kuslich removes the entire annulus fibrosus as well as nuclear tissue at that entrance bore (46) to provide an opening for delivery of the device (40), as seen in Figure 4. (Note that the anterior annulus (30) is no longer present.) After creating the entrance bore (46), the bag device (40) is then delivered into the hollow chamber (44) and fully expanded by filling the bag via the bag fill opening (48) with fill material, causing separation of the vertebral bodies and thus stabilization of the spinal segment. (See, col. 7, lines 26-31). This bag fill opening (48), along with the knot (58) that closes the opening (48), is what appears to reside within the entrance bore (46), as shown above in Fig. 10. With the bag (40) fully expanded, the knot (58) serves to close the bag and "prevent egress of fill material." (See, col. 9, lines 37-39). In fact, Kuslich's implant device (40) requires a fill opening closure means, such as knot (58), in order for it to perform its intended purpose of spinal stabilization. Accordingly, the sole purpose of the bag opening (48) and knot (58) is to maintain graft material within the bag device (40), a critical requirement for the Kuslich device (40), to maintain the device's rigidity and internal pressure. The equatorial band (42) of device 40 further supports the rigidity of the implant, in use, by restricting the equatorial expansion of the device while encouraging polar expansion of the device along the long axis of the spine to cause the separations of vertebral bodies. (See, col. 4, lines 12-16). The equatorial band (42) of Kuslich's device (40) plays no

role in treating the annulus; but rather facilitates this separation of vertebral bodies with his device (40).

Nowhere does Kuslich teach or suggest that the bag opening (48), which is what the Examiner has referred to as that portion of the equatorial band (42) residing within the entrance bore (46), forms a bridge for the traverse of cells in the treatment of an aperture in the annulus fibrosus. In fact, it is unclear from Fig. 10 where the bag opening (48) and knot (58) actually reside with respect to the patient's anatomy, since Kuslich has removed all of the annulus fibrosus and nuclear tissue in that area. However, what is clear is that Kuslich's device (40) with its bag opening (48) and knot (58) is not a therapeutic or prophylactic device for treating a spinal disc annulus, as is claimed by Applicants. Simply put, Kuslich's device (40) does not treat or repair an annulus fibrosus. For these reasons, Applicants believe that Kuslich fails to anticipate the claimed invention because Kuslich does not provide a device for treating a spinal disc annulus having an aperture, comprising a biocompatible material for placement in and across the aperture, forming a bridge to provide a platform for the traversal of cells to facilitate tissue growth.

For all of the aforementioned reasons, Applicants believe that Kuslich fails to anticipate the claimed invention since Kuslich clearly fails to satisfy each and every limitation of amended independent claim 21. The Examiner is kindly asked to reconsider and withdraw the rejection under Kuslich in view of the amendment and these remarks.

The Ferree and Bao Patents are Not Proper 102(e) References

For all the reasons set forth in the attached Rule 131 Declaration of Joseph C. Cauthen, neither the Ferree or Bao patents are prior art to the present application under 35 U.S.C. §102(e). Accordingly, Applicant respectfully requests withdrawal of the rejections under Ferree and Bao.

The Ferree and Bao Patents are Not Prior Art

As set forth in the attached Declaration, Joseph C. Cauthen had conceived of the invention prior to the filing date of both the Ferree patent and the Bao patent. This conception is based on an actual surgery performed by Dr. Cauthen prior to the May 28, 1999 filing date of the Ferree patent, and the May 29, 1998 filing date of the Bao patent. After this date of conception, Dr. Cauthen was reasonably diligent in practicing the invention until he successfully reduced the invention to practice on a date no later than April 15, 1999. Among the evidence indicating Dr. Cauthen's reasonable diligence during this period are the additional surgeries using the present invention, and the collection and analysis, under Dr. Cauthen's supervision, of follow-up data from actual patients of Dr. Cauthen undergoing surgery according to the claimed invention. As discussed below, the actual reduction to practice of this invention is documented by Dr. Cauthen's submission of an abstract to the Congress of Neurological Surgeons (CNS) on April 15, 1999 in advance of the conference that CNS held in Boston later that year. In addition to the April 15, 1999 abstract, Dr. Cauthen also submitted an earlier abstract on September 4, 1998 to the American Association of Neurological Surgeons and the

Congress of Neurological Surgeons (AANS/CNS) for a poster presentation held in Orlando, Florida in February 1999.

Both the September 4, 1998 and the April 15, 1999 abstracts clearly document the conception of the claimed method. Specifically, these abstracts set forth annular disc repair including accessing the subannular space (e.g., following initial lumbar discectomy), and placing fascial autograft tissue subannularly beneath an opening in the annulus fibrosus. According to the invention, the placement of a therapeutic or prophylactic device, e.g., a fascial autograft, beneath the rent, lesion or incision in the annulus helps avoid reherniations, where the nucleus pulposus again extrudes out of the annulus and impinges against nerves. Before the filing date of the Bao patent, Dr. Cauthen had conceived of a technique of preventing reherniations by placing a therapeutic or prophylactic device, e.g., fascial autograft, subannularly in and across the opening to help resist any future extrusion of nuclear disc material and provide a bridge for cells to traverse the rent, lesion or incision to enhance natural healing. As described in these abstracts, one method Dr. Cauthen explored was the use of subannular suture loops placed on either side of an annular opening, which could be pathologic (annular defect) or surgical, and then inserting a therapeutic or prophylactic device of fascial tissue into the subannular space, in and across the opening, and securing the device with the subannular suture loops. It is also pointed out that Dr. Cauthen used autograft in his experiments that were reported in the CNS abstract, but that the material forming the therapeutic or prophylactic device, whether natural (e.g., autograft, allograft, xenograft, etc.) or synthetic is not critical to the practicing of the invention.

Taken together, these abstracts reflect Dr. Cauthen's continued efforts to successfully reduce the invention to practice and perfect the claimed methods and devices. The earlier September 4, 1998 abstract to AANS/CNS documents the early data collected using the present invention and beginning with the first surgery performed before May 29, 1998, but does not conclusively prove that the invention worked as Dr. Cauthen intended. With continued practice of the invention and a larger control group and body of follow-up data, Dr. Cauthen was then able to conclude his invention did work as intended, as evidenced by his April 15, 1999 abstract to CNS documenting the positive data from his surgeries. Actual reduction to practice, therefore, occurred no later than April 15, 1999.

Having established Dr. Cauthen's conception prior to May 29, 1998, and reasonable diligence from conception through actual reduction to practice, it is respectfully submitted that both the Ferree patent and the Bao patent are not prior art against the present claimed invention. Applicant respectfully requests withdrawal of the separate rejections of claims 20-22 over Ferree and Bao, respectively.

Information Disclosure Statement

Applicant hereby provides an Information Disclosure Statement under 37 C.F.R. §1.97(c) listing additional information related to the presently claimed invention for the Examiner's consideration.

Conclusion

In view of the foregoing amendments and remarks, Applicant respectfully requests reconsideration and reexamination of this application and the timely allowance of the pending claims.

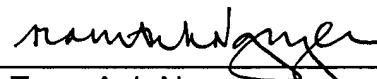
Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: December 2, 2004

By: _____


Tram Anh Nguyen
Reg. No. 47,257

Attachments:

Petition and Fee for Extension of Time
Declaration of Joseph C. Cauthen under 37 C.F.R. §1.131 (w/ Exhibits A-H)
Information Disclosure Statement under 37 C.F.R. §1.97(c) (w/ Exhibits A-D)
Cauthen Timeline

413269.1

Subject: Microsurgical Annular Reconstruction (Annuloplasty) Following Lumbar Microdiscectomy: Preliminary Report of a New Technique

Date: Fri, 04 Sep 1998 14:35:21 GMT

From: abstracts@neurosurgery.org

To: aliallen@mindspring.com

<P>Confirmation of Online Abstract Submission</P>

<P>AANS/CNS Section on Disorders of the Spine & Peripheral Nerves Annual Meeting</P>

<P>TITLE: Microsurgical Annular Reconstruction (Annuloplasty) Following Lumbar Micro

<P>AUTHORS: Joseph C. Cauthen, MD</P>

<P>ABSTRACT:</P>

<P> INTRODUCTION. Any new method offering a prospect of lowering discal reherni
Modification of the standard technique incorporates: (1) slit annulotomy and, f
TECHNIQUE. The procedure employs standard unilateral laminotomy and micro-oper
RESULTS. Literature reports of symptomatic recurrent disc herniation requiring
CONCLUSION. Microsurgical annular reconstruction following lumbar microdissect
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<P>Your username is: Joseph</P>

<P>Your password for this abstract is: spine99-180</P>

<P>Please save this email. You will need this information to make
changes to your abstract if necessary.</P>

Microsurgical Annular Reconstruction (Annuloplasty) Following Lumbar Microdiscectomy: Preliminary Report of a New Technique

Joseph C. Cauthen, M.D.

Introduction. Any new method offering a prospect of lowering discal reherniation rates and subsequent reoperation after lumbar discectomy deserves consideration by spine surgeons. An operative technique to reconstruct the annulus following lumbar microdiscectomy has been developed. Since nuclear herniation occurs through an annular defect, intuition suggests that the rate of reherniation following initial discectomy can be reduced by closing the annular defect.

Modification of the standard technique incorporates: (1) slit annulotomy and, following disc fragment removal, (2) annuloplasty using one or two sutures alone or (3) adding subannular fascial autograft prior to suture closure of the annular defect.

Technique. The procedure employs standard unilateral laminotomy and micro-operative technique for retrieval of herniated nuclear fragments, either in the epidural or subannular spaces. If an annular defect is present, extruded and interspace fragments are removed as required, preparatory to annulus closure. In the intact attenuated annulus, slit annulotomy is performed utilizing a 5-8 mm sharp incision at annular midpoint equidistant from endplates. Annuloplasty requires placement of 4-0 absorbable sutures on half-circle needles equidistant along the annulotomy opening and microsurgical knot-tying technique. A fascial autograft is secured in the subannular loop of the sutures used to close the annulotomy incision. With experience, additional operative time required is less than thirty minutes.

Results. Literature reports of symptomatic recurrent disc herniation requiring reoperation are 1.3-21% (Branch CL. *Clin. Neurosurg.* 1995;18:252-267). To date, annuloplasty results are: one suture (reherniation in 7/40=17.5%); two or more sutures (2/42=4.7%); multiple sutures with fascial autograft (1/32=3.1 %).

Conclusion. Microsurgical annular reconstruction following lumbar microdiscectomy may prove valuable as this technique continues to evolve.

2/8/99

ANNULOTOMY STUDY

PRELIMINARY RESULTS: UPDATED 2/99

for
all procedures with at least one-year follow-up

RECURRENCES

TECHNIQUE	TOTAL PROCEDURES (N)	PROCEDURES W/ ONE-YR FOLLOW-UP (N)	RECURRENT DISC HERNIATIONS (N)	RECURRENCE RATE (%)	AVERAGE FOLLOW-UP (YRS)	AVERAGE TIME TO RECURRENCE (YRS)
DISCECTOMY WITHOUT ANNULOTOMY	64	64	11	17%	5.2 (4.6 - 5.7)	0.7 (0.1 - 1.8)
ONE SUTURE	41	41	9	22%	3.7 (2.1 - 4.8)	1.2 (0.2 - 2.9)
TWO SUTURES	46	46	5	11%	3.0 (1.3 - 4.5)	1.2 (0.1 - 2.0)
FASCIAL AUTOGRAFT	33	17*	1	6%	1.4 (1.1 - 1.7)	1.0 (1.0 - 1.0)

* 16 procedures have <1 yr follow-up.

FULL TEXT OF CASES (USPQ2D)
All Other Cases

TP Laboratories, Inc. v. Professional Positioners, Inc. et al. (CA FC)
220 USPQ 577 TP Laboratories, Inc. v. Professional Positioners, Inc. et
al.

U.S. Court of Appeals Federal Circuit
220 USPQ 577

Decided Jan. 4, 1984
Nos. 83-660 and 83-680

Headnotes

PATENTS

1. Patentability/Validity -- Anticipation -- In general (§ 115.0701)

General purpose behind public use bars to patentability under 35 USC 102 is to require inventors to assert with due diligence their right to patent through prompt filing of patent application.

2. Patent grant -- In general (§ 105.01)

Operating against inventor who seeks patent are policies of protecting public in its use of invention where such use began prior to filing of application, encouraging prompt disclosure of new and useful information, and discouraging attempts to extend length of period of protection by not allowing inventor to reap benefits for more than one year prior to filing of application; in contrast to these considerations, public interest is also deemed to be served by allowing inventor time to perfect his invention, by public testing, if desired, and to prepare patent application.

3. Patentability/Validity -- Anticipation -- Prior use -- Experimental use (§ 115.0706.05)

City of Elizabeth v. American Nicholson Pavement Co., 97 US 126 (1877), which states that it is not public knowledge of his invention that precludes inventor from obtaining patent for it, but public use or sale of it, is starting place for analysis of any case involving experimental use; Court there did not refer to experimental use as exception to bar otherwise created by public use; more precisely, Court reasoned that if use is experimental, even though not secret, public use is negated; difference between "exception" and "negation" is not merely semantic.

4. Patentability/Validity -- In general (§ 115.01)**Patentability/Validity -- Anticipation -- Prior use -- Experimental use (§ 115.0706.05)**

Statutory presumption of validity provided in 35 USC 282 places burden of proof upon party attacking validity of patent, and that burden of persuasion does not shift at any time to patent owner; it is constant and remains throughout suit on challenger; under this analysis it is incorrect to impose on patent owner burden of proving that public use was experimental; these are not two separable issues; it is incorrect to ask, "Was it public use?" and then "Was it experimental?"; rather, court is faced with single issue -- was it public use under 35 USC 102(b)?

5. Patentability/Validity -- Anticipation -- Prior use -- Experimental use (§ 115.0706.05)

Fact that court should have looked at all evidence put forth by both parties and should have decided whether entirety of evidence led to conclusion that there had been public use, does not mean that challenger has burden of proving that use is not experimental; nor does it mean that patent owner is relieved of explanation; it means that if prima facie case is made of public use, patent owner must be able to point to or must come forward with convincing evidence to counter that showing.

6. Patentability/Validity -- Anticipation -- Prior use -- Experimental use (§ 115.0706.05)

Length of test period is merely piece of evidence to add to evidentiary scale; same is true with respect to whether payment is made for device; whether user agreed to use secretly, whether records were kept of progress, whether persons other than inventor conducted asserted experiments, how many tests were conducted, how long testing period was in relationship to tests of other similar devices; in other words, decision on whether there was public use can only be made upon consideration of entire surrounding circumstances.

7. Patentability/Validity -- Anticipation -- Prior use -- Experimental use (§ 115.0706.05)

While various objective indicia may be considered in determining whether use is experimental, expression by inventor of his subjective intent to experiment, particularly after institution of litigation, is generally of minimal value.

8. Patentability/Validity -- Anticipation -- Prior use -- Experimental use (§ 115.0706.05)

That non-secret uses of device were made prior to critical date is not itself dispositive of issue of whether activity barring patent under 35 USC 102(b) occurred; fact that device was not hidden from view may make use not secret,

but non-secret use is not ipso facto public use activity; nor is all secret use ipso facto not public use within meaning of statute, if inventor is making commercial use of invention under circumstances that preserve its secrecy.

9. Patentability/Validity -- Anticipation -- Prior use -- Experimental use (§ 115.0706.05)

In some circumstances it would be significant to issue of experimental use that no pledge of confidentiality was obtained from user of device during alleged period of experimentation; in circumstances of use by orthodontal patients of corrective "appliance", no importance attaches to fact that doctor did not ask patient to swear to secrecy; testing of device had to be public to some extent and it is beyond reasonable probability that patient would show device to others who would understand its function or would want to duplicate it; pledge of confidentiality indicative of inventor's continued control is established inherently by dentist-patient relationship of parties; routine checking of patients by other orthodontists associated with inventor does not indicate inventor's lack of control or abandonment to public.

10. Patentability/Validity -- Anticipation -- Prior use -- Experimental use (§ 115.0706.05)

Fact that during critical time inventor had readily available all facilities to exploit device, yet offered none of devices to competitors, even though this was one facet of his total business activity, and that he made no extra charge to users of device, are factors supporting experimental use, although last factor is not itself critical; such facts indicate inventor was testing device, not market; no commercial exploitation having been made to even small degree prior to patent application, underlying policy of prohibiting extension of term is not offended.

Particular Patents -- Orthodontal Devices

3,178,820, Kesling, Molded Tooth Positioning Appliance, holding of invalidity reversed.

Case History and Disposition:

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Consolidated appeals from District Court for Eastern District of Wisconsin, Warren, J.

Action by TP Laboratories, Inc., against Professional Positioners, Inc. (Wisconsin), Professional Positioners, Inc. (Delaware), Gerald W. Huge, and Richard W. Allessee, for patent infringement. From judgment for defendant in part, both parties appeal. Affirmed in part, reversed in part and remanded.

Attorneys:

Lloyd L. Zickert, Chicago, Ill. (Glenn W. Ohlson, Chicago, Ill., on the brief), for plaintiff.

Allan B. Wheeler, Milwaukee, Wis., for defendants.

Judge:

Before Markey, Chief Judge, Skelton, Senior Circuit Judge, and Nies, Circuit Judge.

Opinion Text**Opinion By:**

Nies, Circuit Judge.

These appeals are from the October 27, 1982 judgment of the United States District Court for the Eastern District of Wisconsin (Warren, J.) dismissing a charge of infringement of a patent for an orthodontic appliance. Sitting without a jury, the court held U.S. Patent No. 3,178,820 ('820), owned by TP Laboratories, Inc. (TP), invalid under 35 U.S.C. §102(b), on the ground that a public use occurred more than one year prior to the filing date of the application for the subject patent.

TP appeals the holding of invalidity. TP admits that the inventor used the dental appliance on three orthodontal patients during the critical period but asserts that such use was non-barring experimental use. On this issue we agree with appellant and reverse. However, since the issue of whether the accused devices are infringements, as well as other issues, were not decided, it is necessary to remand.

In the cross-appeal Professional Positioners et al. (PRO) appeal the denial of an award of attorney fees under 35 U.S.C. §285, and seek an increase in the amount awarded under Rule 37(d) of the Fed. R. Civ. P. for costs attributable to TP's late production of certain documents during discovery. We affirm the district court's decisions on these matters.

Our jurisdiction is found in 28 U.S.C. §1295(a)(1).

I

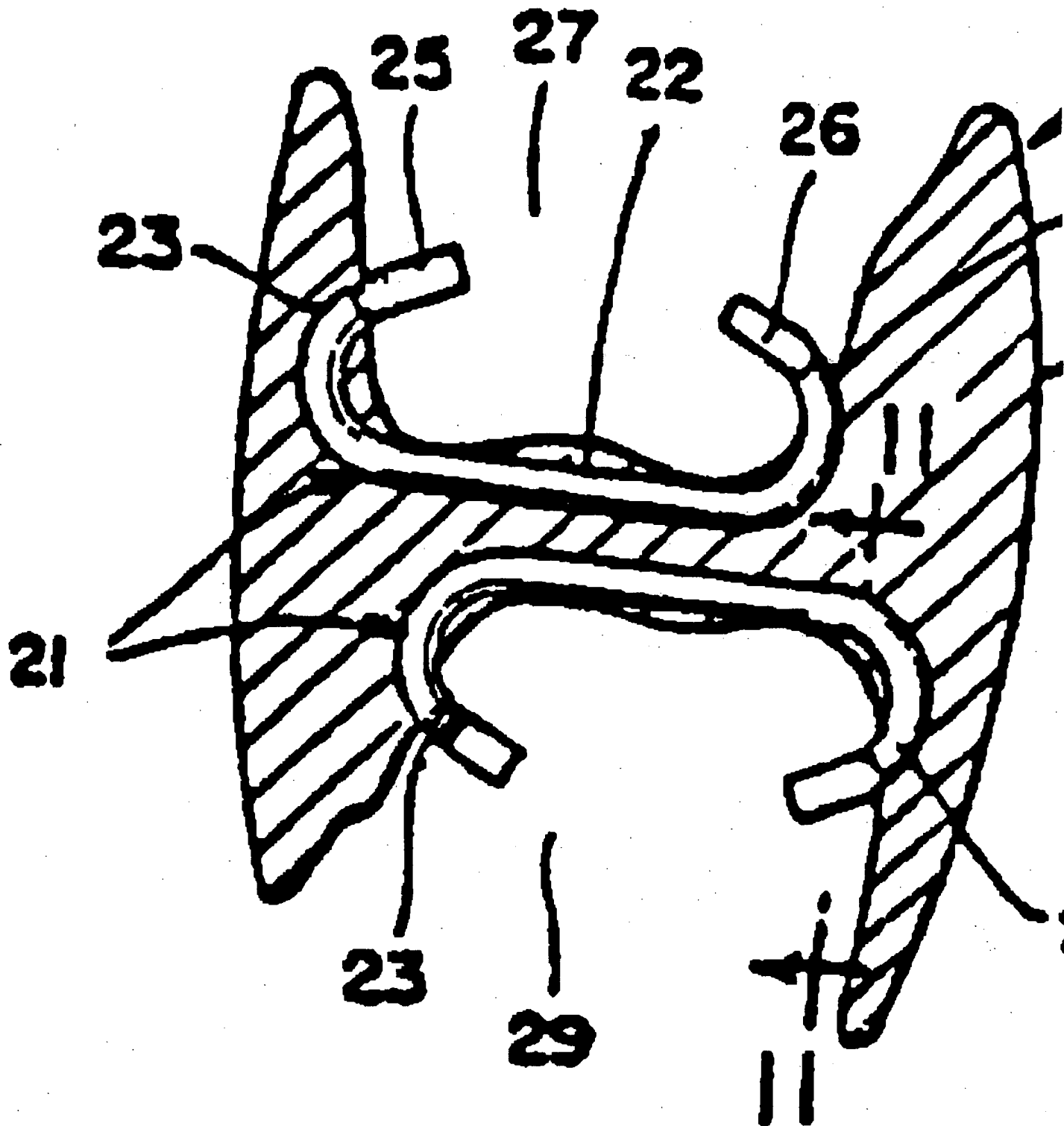
Appellant-plaintiff, TP Laboratories, Inc., makes and sells orthodontic supplies and appliances to the dental profession. TP Laboratories is a separate business from the professional practice of the Kesling and Rocke Orthodontic Group (K&R), a group of four orthodontists, Doctors Harold D. Kesling, Robert A. Rocke, Peter C. Kesling and David L. Kesling, but the firms are closely connected. The record before us shows that Dr. Harold Kesling, now deceased, (Kesling), who is the inventor named in the patent in suit, was an officer and one of the owners of TP Laboratories. Dr. Peter Kesling is president.

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The two businesses share a small building and employ the same office manager.

Kesling conceived and made the first prototype of the invention of the patent in suit in 1956. It was not, however, until February 19, 1962, that Kesling filed a patent application on his invention for which the '820 patent was granted on April 20, 1965. On November 1, 1965, the patent was assigned to TP Laboratories.

The subject matter of the '820 patent is a molded tooth positioning appliance which is to be worn several hours a day by a person undergoing orthodontal treatment. The general type of device is not new. The improvement by Kesling lies in placing wires in the device which fit in the embrasure area between the teeth and keep the appliance in position without the necessity of the patient exerting constant jaw pressure. The wires are referred to as "seating devices," "seating springs," "precision seating springs," "springs," or "metal adjuncts." Because of the shape, as seen below, the invention is also referred to as a tooth positioner with "C's":



This figure is a transverse sectional view illustrating one form of positioning means or clip employed for obtaining proper positioning of the dental appliance in a person's mouth.

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<http://www.bna.com/corp/index.html#V>

The use of tooth positioners with C's in the treatment of three K&R patients during the period 1958-61 led to the issues under 35 U.S.C. §102(b). It is undisputed that these three devices fell within the language of the '820 claims and no modification of design was made as a consequence of these uses. The evidence which established these uses was found in the patient records of K&R and the underlying facts are not in dispute. Appellant characterizes these uses as secret and/or experimental; appellees urge that they are, as found by the district court, public uses within the meaning of the statute.

The first use of the claimed invention on a patient occurred on August 25, 1958. Orthodontal treatment of this patient (Furst) spanned the time period between February 1958 and April 1964. Use of the device terminated after approximately two months. During discovery, the device itself was produced, having been retained by K&R in the patient's model box. This patient's mandibular model from the model box was inscribed "experimental wires." Over the six year period of treatment, this patient was also fitted with other devices, retainers as well as positioners not embraced by the '820 claims.

Another patient (Rumely-Brady) who had begun treatment in August 1958 was supplied with a tooth positioner equipped with C's on November 10, 1959. Entry on the record card of this patient indicates "results fair" on December 18, 1959; "results better" on February 5, 1960, and "results good" on August 1, 1960. Nevertheless, use of the device was discontinued on January 16, 1961, in favor of retainers, because certain spacing irregularities were not being corrected. The same positioner with C's was again prescribed on May 5, 1961, and was used in conjunction with various other devices until at least March of 1962. The patient missed a later scheduled appointment which is the last entry on her card.

A positioner with C's was prescribed for a third patient (Spiers-Elliott) on November 1, 1960. Its use apparently was discontinued about three months later, a different device being mailed to the patient on February 2, 1961.

During the treatment of this patient, which spanned the period of time between January 21, 1960, and November 24, 1961, three different positioners were prescribed, only one of which was embraced by the '820 claims.

The initial use in each of the above cases occurred prior to the critical date of February 19, 1961. During the years 1958-60, K&R placed 606 tooth positioners, of which only the three described above were within the claims of '820. In 1961, after the critical date, 28 tooth positioners with C's were prescribed by K&R out of a total of 151.

The above devices were made for the K&R patients by TP, including C's handmade by Kesling. There is no evidence that K&R charged patents specifically for any positioner. With two of the three patients, K&R followed its regular practice of setting a fixed total fee for professional services, which included necessary appliances. One patient (Furst), whose father was a dentist, received free treatment as a professional courtesy.

Sales of the patented device to other orthodontists began in 1966, that is, only after TP's acquisition of the patent.

Appellees, Hugel and Allessee, had no knowledge of the invention even though employed at TP prior to 1961.

The district court did not rule on whether appellees' allegedly infringing devices came within the scope of the claims of the '820 patent and we know only that infringement is charged since 1972.

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II

A

The patent statute provides in pertinent part in 35 U.S.C. §102:

A person shall be entitled to a patent unless --

(b) the invention was * * * in public use * * * in this country, more than one year prior to the date of the application for patent in the United States.

Decisions under this provision and comparable provisions in earlier statutes are marked by confusion and

inconsistency. 1

[1] [1] "The general purpose behind all the [102(b)] bars is to require inventors to assert with due diligence their right to a patent through the prompt filing * * * of a patent application." 2 D. Chisum, Patents §601 (1981 & Supp. 1983).

[2] [2] More specifically, courts have discerned a number of factors which must be weighed in applying the statutory bar of §102(b). 2 Operating against the inventor are the policies of 1) protecting the public in its use of the invention where such use began prior to the filing of the application, 2) encouraging prompt disclosure of new and useful information, 3) discouraging attempts to extend the length of the period of protection by not allowing the inventor to reap the benefits for more than one year prior to the filing of the application. In contrast to these considerations, the public interest is also deemed to be served by allowing an inventor time to perfect his invention, by public testing, if desired, and prepare a patent application.

The district court's consideration of the issue of public use proceeded according to the following two-step analysis: Consequently, the first step in analyzing Pro's 35 U.S.C. §102(b) assertion is to determine whether a public use occurred. If a public use is found, then the Court must ascertain whether the use was not a public use under the statute because it was experimental.

As to the first step, the district court reasoned:

The evidence in this case clearly establishes use by at least three patients more than one year prior to the application date. Furthermore, these users were "under no limitation, restriction or obligation of secrecy to the inventor." *Randolph v. Allis-Chalmers Manufacturing Co.*, 264 F.2d at 535 [120 USPQ at 513]. Certainly there is no evidence to the contrary and there is testimony to support such a finding * * * * Consequently, the Court can only conclude that the patients were under no obligations of secrecy or for that matter any restrictions.

TP argues that these items were in secret because even the patients were not aware of the "testing." This is not significant. The plain fact is that the claimed invention was not kept secret. It was open to public observation without restriction which is sufficient to constitute "public use." See *Egbert v. Lippmann*, 104 U.S. 333 (1881). Furthermore, Dr. Furst was aware that the precision seating springs were a new device * * * * In addition, several of Mrs. Spiers Elliott's associates saw the device. Consequently, the feigned secrecy relied upon by TP accords it no aid in claiming that the "use" was not "public."

On the second issue as perceived by the district court, the court placed a heavy burden of proof on the patent owner to prove that the inventor's use had been experimental and expressly found that TP did not carry that "burden." In the words of the court:

The inventor bears a heavy burden of showing that the public use was bona fide experimentation.

The experimental exception is unavailable to plaintiff TP for two reasons. First, the evidence presented does not establish that the patentee was conducting a bona fide experiment. On the contrary, the record shows that the uses were random and poorly monitored. The only records kept by Dr. H. Kesling were the patient records. Dr. H. Kesling, the inventor, did not always evaluate how well the precision seating springs worked when the patients visited the clinic. Other doctors often made evaluations of performance. Furthermore,

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while the issue of experimentation is in effect a matter of the inventor's intent, in the present case the evidence indicates that his intent was not experimentation. In experimenting on a prior "invention," Dr. H. Kesling kept accurate records of the results of his experiments. In the present case, the records are scanty at best.

It is important to note that the burden was on the plaintiff TP to show that use was a genuine experiment. Accurate records of the results of an experiment are certainly an indicia that the use was a bona fide experiment. In contrast the dearth of such records indicate that the use was not an experiment. The experimental use exception "is to be guarded closely." *Atlas Chemical Industries, Inc. v. Moraine Products*, [509 F.2d 1, 4] 184 USPQ 281, 283 (6th Cir. 1974). TP has simply failed to prove that the inventor, Dr. H. Kesling, was conducting a bona fide

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experiment.

Assuming, however, that the use was experimental, the delay in filing the patent application was unreasonable. The first use of the invention was in August of 1958. By April of 1959, Dr. H. Kesling knew that the precision seating sprigs operated as designed * * * Nevertheless, Dr. H. Kesling waited until February 19, 1962 to file his patent application. Significantly, the claimed invention disclosed in figure 7 of the patent in suit is substantially the same as the precision seating spring disclosed in the positioner * * * supplied to Nancy Furst in August of 1958.

The delay here was unreasonable because the device proved satisfactory immediately. At least as early as 1960 Dr. Kesling learned that the invention was workable. At that point his time began to run under 35 U.S.C. §102(b). Even if he had made minor improvements over the period, all this Court needs [sic] find is that the application was filed more than one year after the basic invention was disclosed within the meaning of section 102(b). *Franz Manufacturing Co. v. Phenix Manufacturing Co.*, 457 F.2d 314 [173 USPQ 266] (7th Cir. 1972). This Court is of the opinion that when an experiment tolls section 102(b), the one-year period of limitations commences to run when the invention disclosed proves workable.

We disagree with this analysis and the shift in the burden of proof which led the district court to an erroneous result.

B

It is not public knowledge of his invention that precludes the inventor from obtaining a patent for it, but a public use or sale of it.

[3] [3] The above quotation is from *City of Elizabeth v. American Nicholson Pavement Co.*, 97 U.S. 126, 136 (1877), which is the starting place for analysis of any case involving experimental use. There, a toll road, built according to the invention of the patent in suit, was in daily use for a period of 6 years before the inventor filed for a patent. In upholding the validity of the patent, the Supreme Court spoke with clarity but through the years the guidelines set forth therein have been obfuscated. Returning to the original, we quote the following passages which are particularly pertinent to our analysis here:

That the use of the pavement in question was public in one sense cannot be disputed. But can it be said that the invention was in public use? The use of an invention by the inventor himself, or of any other person under his direction, by way of experiment, and in order to bring the invention to perfection, has never been regarded as such a use. *Curtis*, Patents, sect. 381; *Shaw v. Cooper*, 7 Pet. 292.

Now, the nature of a street pavement is such that it cannot be experimented upon satisfactorily except on a highway, which is always public.

When the subject of invention is a machine, it may be tested and tried in a building, either with or without closed doors. In either case, such use is not a public use, within the meaning of the statute, so long as the inventor is engaged, in good faith, in testing its operation. He may see cause to alter it and improve it, or not. His experiments will reveal the fact whether any and what alterations may be necessary. If durability is one of the qualities to be attained, a long period, perhaps years, may be necessary to enable the inventor to discover whether his purpose is accomplished. And though, during all that period, he may not find that any changes are necessary, yet he may be justly said to be using his machine only by way of experiment; and no one would say that such a use, pursued with a bona fide intent of testing the qualities of the machine, would be a public use, within the meaning of the statute. So long as he does not voluntarily allow others to make it and use it, and so long as it is not on sale for general use, he keeps the invention under his own control, and does not lose his title to a patent. It would not be necessary, in such a case, that the machine should be put up and

used only in the inventor's own shop or premises. He may have it put up and used in the premises of another, and

the use may inure to the benefit of the owner of the establishment. Still, if used under the surveillance of the inventor, and for the purpose of enabling him to test the machine, and ascertain whether it will answer the purpose intended, and make such alterations and improvements as experience demonstrates to be necessary, it will still be a mere experimental use, and not a public use, within the meaning of the statute.

Whilst the supposed machine is in such experimental use, the public may be incidentally deriving a benefit from it. If it be a grist-mill, or a carding-machine, customers from the surrounding country may enjoy the use of it by having their grain made into flour, or their wool into rolls, and still it will not be in public use, within the meaning of the law.

But if the inventor allows his machine to be used by other persons generally, either with or without compensation, or if it is, with his consent, put on sale for such use, then it will be in public use and on public sale, within the meaning of the law.

97 U.S. at 134-35.

In the decision on appeal, the trial court looked for proof of an exception to the public use bar. However, in *Elizabeth*, the Supreme Court did not refer to "experimental use" as an "exception" to the bar otherwise created by a public use. More precisely, the Court reasoned that, if a use is experimental, even though not secret, "public use" is negated. This difference between "exception" and "negation" is not merely semantic. Under the precedent of this court, the statutory presumption of validity provided in 35 U.S.C. §282 places the burden of proof upon the party attacking the validity of the patent, and that burden of persuasion does not shift at any time to the patent owner. It is constant and remains throughout the suit on the challenger. As stated in *Richdel, Inc. v. Sunspool Corp.*, 714 F.2d 1573, 1579, 219 USPQ 8, 11-12 (Fed. Cir. 1983):

35 USC 282 *permanently* places the burden of proving facts necessary to a conclusion of invalidity on the party asserting such invalidity. *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 218 USPQ 871 (Fed. Reg. 1983); *Solder Removal*, supra, 582 F.2d at 633, 199 USPQ at 133.

[4] [4] Under this analysis, it is incorrect to impose on the patent owner, as the trial court in this case did, the burden of proving that a "public use" was "experimental." These are not two separable issues. It is incorrect to ask: "Was it public use?" and then, "Was it experimental?" Rather, the court is faced with a single issue: Was it public use under §102(b)?

[5] [6] [5,6] Thus, the court should have looked at all of the evidence put forth by both parties and should have decided whether the entirety of the evidence led to the conclusion that there had been "public use." This does not mean, of course, that the challenger has the burden of proving that the use is not experimental. Nor does it mean that the patent owner is relieved of explanation. It means that if a *prima facie* case is made of public use, the patent owner must be able to point to or must come forward with convincing evidence to counter that showing. 3 See *Strong v. General Electric Co.*, 434 F.2d 1042, 1044, 168 USPQ 8, 9 (5th Cir. 1970). The length of the test period is merely a piece of evidence to add to the evidentiary scale. The same is true with respect to whether payment is made for the device, whether a user agreed to use secretly, whether records were kept of progress, whether persons other than the inventor conducted the asserted experiments, how many tests were conducted, how long the testing period was in relationship to tests of other similar devices. In other words, a decision on whether there has been a "public use" can only be made upon consideration of the entire surrounding circumstances.

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[7] [7] While various objective indicia may be considered in determining whether the use is experimental, the expression by an inventor of his subjective intent to experiment, particularly after institution of litigation, is generally of minimal value. In *re Smith*, 714 F.2d at 1127, 218 USPQ at 976.

C

[8] [8] Applying the principles set forth above to this case, that non-secret uses of the device were made prior to the critical date is not in itself dispositive of the issue of whether activity barring a patent under 35 U.S.C. §102(b) occurred. *Minnesota Mining & Manufacturing Co. v. Johnson & Johnson*, 179 USPQ 216, 220 (N.D. Ill 1973). The fact that the device was not hidden from view may make the use not secret but non-secret use is not ipso facto "public use" activity. *City of Elizabeth v. American Nicholson Pavement Co.*, 97 U.S. at 136. Nor, it must be added, is all secret use ipso facto not "public use" within the meaning of the statute, if the inventor is making commercial use of the invention under circumstances which preserve its secrecy.

[9] [9] Turning to the instant case, we note first that disclosure of the seating device to patients could not be avoided in any testing. In some circumstances, no doubt it would be significant that no pledge of confidentiality was obtained from the user. In the circumstances of use by orthodontal patients, we attach no importance to the fact that the doctor did not ask a patient to swear to secrecy. As in *City of Elizabeth*, testing of the device had to be public to some extent and it is beyond reasonable probability that a patient would show the device to others who would understand the function of the C's or would want to duplicate the device. One is all that is needed and, if lost or broken, the patient would expect it to be replaced by the treating dentist.

In any event, a pledge of confidentiality is indicative of the inventor's continued control which here is established inherently by the dentist-patient relationship of the parties. Nothing in the inventor's use of the device on his patients (or the transfer to them) is inconsistent with experimentation. Similarly, the routine checking of patients by one of the other K&R orthodontists does not indicate the inventor's lack of control or abandonment to the public.

Secondly, the finding is clearly erroneous that the invention "proved satisfactory immediately," or "by April of 1959." In this connection, it is noted that the '820 patent itself describes a utility of the patented device for correcting orthodontal irregularities as "urging teeth into preselected positions." The patient records discussed above indicate that treatment to correct such orthodontal irregularities can range from two to six years. Moreover, while results appeared to be good within six months use by one patient, the variable of patient cooperation cannot be checked by one patient alone. Use on three patients is not an obviously excessive number. In other words, the test for success of the improvement was not whether it could be used at all, but whether it could be said to work better on patients than a positioner without C's. Again, as in *City of Elizabeth*, the test of necessity had to run for a considerable time and on several patients before the inventor could know whether "it was what he claimed it to be" and would "answer the purpose intended."

[10] [10] A factor in favor of the patentee is that during this critical time the inventor had readily available all of the facilities of TP to commercially exploit the device. Yet, no positioners with C's were offered competing orthodontists despite the fact this was one facet of the inventor's total business activity. Further, the inventor made no extra charge for fitting the three patients with the improved positioners although that in itself is not critical. The facts here indicate the inventor was testing the device, not the market. No commercial exploitation having been made to even a small degree prior to filing the patent application, the underlying policy of prohibiting an extension of the term is clearly not offended in this respect.

Indeed, none of the policies which underlie the public use bar and which, in effect, define it have been shown to be violated. At most, the record shows that the uses were not secret, but when the evidence as to the facts of use by the inventor is considered as a whole, we conclude that appellees failed to prove that the inventor made a public use of the subject invention within the meaning of 35 U.S.C. §102(b). The patent may not be held invalid on this ground.

III

Fees Under Rule 37(d) of the Fed. R. Civ. P.

No error or abuse of discretion is found in the award of fees to appellees under Rule 37(d) or in the amount of the award. Appellant's premise that no order of the court was violated by its failing to produce certain invoices ignores

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the scope of the December 31, 1975 order. In PRO's motion leading to that

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order "All invoices * * * to Kesling-Rocke Orthodontic Center" were specifically designated and thus, the withheld invoices fall under its terms.

IV

PRO's cross-appeal from the district court's denial of attorney fees under 35 U.S.C. §285 is dismissed as moot. In view of our disposition of the appeal, PRO is no longer a prevailing party to whom an award should be made. *Stickle v. Heublein, Inc.*, 716 F.2d 1550, 1564, 219 USPQ 377, 386 (Fed. Cir. 1983).

Summary

The decision of the district court holding U.S. Patent No. 3,178,820 invalid is reversed. The decision of the court awarding costs and fees under Rule 37(d) is affirmed. The cross-appeal is dismissed. The case is remanded to the district court for proceedings consistent herewith.

Footnotes

Footnote 1. Compare *Watson v. Allen*, 254 F.2d 342, 117 USPQ 68 (DC Cir. 1958) with *In re Blaisdell*, 242 F.2d 779, 113 USPQ 289 (CCPA 1957); See G.T. Welch, Patent Law's Ephemeral Experimental Use Doctrine, 11 Tol. L. Rev. 865-92 (1980); Note, The Public Use Bar to Patentability; Two New Approaches to the Experimental Use Exception, 52 Minn. L. Rev. 851 (1968); Wells & Riggins, Public Use and Sale as a Bar to Obtaining a Patent and Its Application to Government Activities, 18 Am. U. L. Rev. 43, 51-57 (1968); Pigott, The Concepts of Public Use and Sale, 49 J. Pat. Off. Soc'y 399, 411-26 (1967); Comment, Experimentation and Public Use of Inventions -- An Analysis of Appellate Anemia, U. Ill. L. F. 585 (1960); Vassil, Public Use; The Inventor's Dilemma, 36 Geo. Wash. L. Rev. 297 (1958).

Footnote 2. See generally, *In re Smith*, 714 F.2d 1127, 1135, 218 USPQ 976, 983 (Fed. Cir. 1983).

Footnote 3. We do not read *Smith & Griggs Mfg. Co. v. Sprague*, 123 U.S. 249, 267 (1887) as contrary to this view, as urged by appellees. However, assuming that in *Smith & Griggs*, the Court intended to impose the ultimate burden of persuasion on the patent holder rather than merely the burden of going forward with countering evidence, we do not believe that view is tenable in the face of the subsequently enacted statutory presumption. As stated in *Austin Machinery Co. v. Buckeye Traction Ditcher Co.*, 13 F.2d 697, 700 (6th Cir. 1926), where a similar argument was advanced with respect to the meaning of *Smith & Griggs*:

The presumption of the validity of the patent is such that the defense of invention by another must be established by the clearest proof -- perhaps beyond reasonable doubt. The same rule apparently should apply to the defense of prior public use or sale by the inventor. When an actual sale in the critical period appears, it may well be that the trier of fact will mentally shift the burden of evidence necessary to show this sale to have been so modified that its existence did not make the device "on sale" within the meaning of the statute; but we see no reason why the legal burden of proof should shift, and we know of no authoritative and considered decision to that effect. It would seem that the legal and heavy burden of proof as to all the elements involved continues until the end upon one who attacks the patent grant.

- End of Case -

FULL TEXT OF CASES (USPQ2D)

All Other Cases

Pfaff v. Wells Electronics Inc. (US SupCt) 48 USPQ2d 1641 Pfaff v.

Wells Electronics Inc.

**U.S. Supreme Court
48 USPQ2d 1641**

Decided November 10, 1998

No. 97-1130

Headnotes

PATENTS

1. Patentability/Validity -- Date of invention -- Reduction to practice (§ 115.0405)

Patentability/Validity -- Anticipation -- Prior sale -- Degree of development (§ 115.0707.05)

Invention can be "on sale" within meaning of 35 USC 102(b) even if it has not yet been reduced to practice, since on-sale bar of Section 102(b) applies if, prior to critical date, product is subject of commercial offer for sale, and invention is ready for patenting, and since second condition may be satisfied by proof of reduction to practice before critical date, or by proof that prior to critical date inventor had prepared drawings or other descriptions of invention that were sufficiently specific to enable person skilled in art to practice invention.

2. Patentability/Validity -- Date of invention -- Reduction to practice (§ 115.0405)

Patentability/Validity -- Anticipation -- Prior sale -- Degree of development (§ 115.0707.05)

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Invention of patent for computer chip socket was ready for patenting when it was offered for sale more than one year prior to patent's application date, and patent is therefore invalid under 35 USC 102(b) even though invention had not yet been reduced to practice, since manufacturer was able to produce sockets using inventor's detailed drawings and specifications, and since those sockets contained all elements of invention claimed in patent.

Particular patents -- General and mechanical -- Computer chips

4,491,377, Pfaff, mounting housing for leadless chip carrier, judgment holding claims 1, 6, 7, 10, 11, and 19 invalid affirmed.

Case History and Disposition:

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Petition for writ of certiorari to the U.S. Court of Appeals for the Federal Circuit; 43 USPQ2d 1928 .

Action by Wayne K. Pfaff against Wells Electronics Inc. for patent infringement. The U.S. District Court for the Northern District of Texas, Sanders, S.J., held that two claims of patent in suit were invalid for anticipation, that four additional claims were not invalid, and that three of those claims were infringed. The U.S. Court of Appeals for the Federal Circuit reversed in part, holding four of six claims in question invalid under on-sale bar of 35 USC 102(b). On petition of plaintiff-appellant Wayne K. Pfaff for writ of certiorari. Affirmed.

Attorneys:

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C. Randall Bain, Alan H. Blankenheimer, Patricia A. Hubbard, C. Mark Kittredge, and Dan L. Bagatell, of Brown & Bain, Phoenix, Ariz.; James D. Hall, of Baker & Daniels, South Bend, Ind., for respondent.

Jeffrey P. Minnear, assistant to solicitor general, Seth P. Waxman, solicitor general, Lawrence G. Wallace, deputy solicitor general, William Kanter, Alfred Mollin, David Seidman, and Marsk S. Popofsky, U.S. Department of Justice; Nancy J. Linck, solicitor, Albin F. Drost, deputy solicitor, John M. Whealan, and Kevin T. Kramer, associate solicitor, U.S. Patent and Trademark Office, for amicus curiae United States.

SYLLABUS BY THE COURT

Under Section 102(b) of the Patent Act of 1952, no one can patent an "invention" that has been "on sale" more than one year before filing a patent application. In early 1981, petitioner Pfaff designed a new computer chip socket and sent detailed engineering drawings of the socket to a manufacturer. He also showed a sketch of his concept to Texas Instruments, which placed an order for the new sockets prior to April 8, 1981. In accord with his normal practice, Pfaff did not make and test a prototype before offering to sell the socket in commercial quantities. He filled the order in July 1981, and thus the evidence indicates that he first reduced his invention to practice that summer. He applied for a patent on April 19, 1982, making April 19, 1981, the critical date for Section 102(b)'s on-sale bar. After the patent issued, he lost an infringement action he filed against respondent, Wells Electronics, Inc. Subsequently, he brought this suit, alleging that a modified version of Wells' socket infringed

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six of his patent's claims. The District Court held, *inter alia*, that three of the claims were infringed, rejecting Wells' Section 102(b) defense on the ground that Pfaff had filed the patent application less than a year after reducing the invention to practice. In reversing, the Court of Appeals concluded, among other things, that Section 102(b)'s 1-year period began to run when the invention was offered for sale commercially, not when it was reduced to practice.

Held: Pfaff's patent is invalid because the invention had been on sale for more than one year in this country before he filed his patent application.

(a) The primary meaning of "invention" in the Patent Act unquestionably refers to the inventor's conception rather than to a physical embodiment of that idea. The statute contains no express "reduction to practice" requirement, see Sections 100, 101, 102(g), and it is well settled that an invention may be patented before it is reduced to practice. In *The Telephone Cases*, 126 U.S. 1, 535-536, this Court upheld a patent issued to Alexander Graham Bell even though he had filed his application before constructing a working telephone. Applying the reasoning of *The Telephone Cases* to the facts of this case, it is evident that Pfaff could have obtained a patent when he accepted Texas Instruments' order, for at that time he provided the manufacturer with a description and drawings of "sufficient clearness and precision to enable those skilled in the matter" to produce the device, *id.*, at 536.

(b) Pfaff's nontextual argument—that longstanding precedent, buttressed by the interest in providing inventors with a clear standard identifying the onset of the 1-year period, justifies a special interpretation of "invention" in Section 102(b) -- is rejected. While reduction to practice provides sufficient evidence that an invention is complete, the facts of *The Telephone Cases* and this case show that such proof is not necessary in every case.

(c) The on-sale bar applies when two conditions are satisfied before the critical date. First, the product must be the subject of a commercial offer for sale. Here, the acceptance of the purchase order prior to April 8, 1981, makes it clear that such an offer had been made, and there is no question that the sale was commercial. Second, the invention must be ready for patenting. That condition may be satisfied in at least two ways: by proof of reduction to practice before the critical date; or by proof that prior to the critical date the inventor had prepared drawings or other descriptions of the invention that were sufficiently specific to enable a person skilled in the art to practice the invention. This condition is satisfied here because the drawings sent to the manufacturer before the critical date fully disclosed the invention. 124 F.3d 1429 [43 USPQ2d 1928], affirmed.

Judge:

omitted

Opinion Text

Opinion By:
Stevens, J.

Section 102(b) of the Patent Act of 1952 provides that no person is entitled to patent an "invention" that has been "on sale" more than one year before filing a patent application.¹ We granted certiorari to determine whether the commercial marketing of a newly invented product may mark the beginning of the 1-year period even though the invention has not yet been reduced to practice.²

1

On April 19, 1982, petitioner, Wayne Pfaff, filed an application for a patent on a computer chip socket. Therefore, April 19, 1981, constitutes the critical date for purposes of the on-sale bar of 35 U.S.C. Section 102(b); if the 1-year period began to run before that date, Pfaff lost his right to patent his invention.

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Pfaff commenced work on the socket in November 1980, when representatives of Texas Instruments asked him to develop a new device for mounting and removing semiconductor chip carriers. In response to this request, he prepared detailed engineering drawings that described the design, the dimensions, and the materials to be used in making the socket. Pfaff sent those drawings to a manufacturer in February or March 1981.

Prior to March 17, 1981, Pfaff showed a sketch of his concept to representatives of Texas Instruments. On April 8, 1981, they provided Pfaff with a written confirmation of a previously placed oral purchase order for 30,100 of his new sockets for a total price of \$91,155. In accord with his normal practice, Pfaff did not make and test a prototype of the new device before offering to sell it in commercial quantities.³

The manufacturer took several months to develop the customized tooling necessary to produce the device, and Pfaff did not fill the order until July 1981. The evidence therefore indicates that Pfaff first reduced his invention to practice in the summer of 1981. The socket achieved substantial commercial success before Patent No. 4,491,377 (the '377 patent) issued to Pfaff on January 1, 1985.⁴

After the patent issued, petitioner brought an infringement action against respondent, Wells Electronics, Inc., the manufacturer of a competing socket. Wells prevailed on the basis of a finding of no infringement. ⁵ When respondent began to market a modified device, petitioner brought this suit, alleging that the modifications infringed six of the claims in the '377 patent.

After a full evidentiary hearing before a Special Master, ⁶ the District Court held that two of those claims (1 and 6) were invalid because they had been anticipated in the prior art. Nevertheless, the court concluded that four other claims (7, 10, 11, and 19) were valid and three (7, 10, and 11) were infringed by various models of respondent's sockets. App. to Pet. for Cert. 21a-22a. Adopting the Special Master's findings, the District Court rejected respondent's Section 102(b) defense because Pfaff had filed the application for the '377 patent less than a year after reducing the invention to practice.

The Court of Appeals reversed, finding all six claims invalid. 124 F.3d 1429 [43 USPQ2d 1928] (CA Fed. 1997). Four of the claims (1, 6, 7, and 10) described the socket that Pfaff had sold to Texas Instruments prior to April 8, 1981. Because that device had been offered for sale on a commercial basis more than one year before the patent application was filed on April 19, 1982, the court concluded that those claims were invalid under Section 102(b). That conclusion rested on the court's view that as long as the invention was "substantially complete at the time of sale," the 1-year period began to run, even though the invention had not yet been reduced to practice. *Id.*, at 1434. The other two claims (11 and 19) described a feature that had not been included in Pfaff's initial design, but the Court of Appeals concluded as a matter of law that the additional feature was not itself patentable because

it was an obvious addition to the prior art. 7 Given the

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court's Section 102(b) holding, the prior art included Pfaff's first four claims. Because other courts have held or assumed that an invention cannot be "on sale" within the meaning of Section 102(b) unless and until it has been reduced to practice, see, e.g., *Timely Products Corp. v. Arron*, 523 F.2d 288, 299-302 [187 USPQ 257] (CA2 1975); *Dart Industries, Inc. v. E.I. DuPont de Nemours & Co.*, 489 F.2d 1359, 1365, n.11 [179 USPQ 392] (CA7 1973), *cert. denied*, 417 U.S. 933 [182 USPQ 1] (1974), and because the text of Section 102(b) makes no reference to "substantial completion" of an invention, we granted certiorari. 523 U.S. ____ (1998).

II

The primary meaning of the word "invention" in the Patent Act unquestionably refers to the inventor's conception rather than to a physical embodiment of that idea. The statute does not contain any express requirement that an invention must be reduced to practice before it can be patented. Neither the statutory definition of the term in Section 100 8 nor the basic conditions for obtaining a patent set forth in Section 101 9 make any mention of "reduction to practice." The statute's only specific reference to that term is found in Section 102(g), which sets forth the standard for resolving priority contests between two competing claimants to a patent. That subsection provides:

"In determining priority of invention there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other."

Thus, assuming diligence on the part of the applicant, it is normally the first inventor to conceive, rather than the first to reduce to practice, who establishes the right to the patent.

It is well settled that an invention may be patented before it is reduced to practice. In 1888, this Court upheld a patent issued to Alexander Graham Bell even though he had filed his application before constructing a working telephone. Chief Justice Waite's reasoning in that case merits quoting at length:

"It is quite true that when Bell applied for his patent he had never actually transmitted telegraphically spoken words so that they could be distinctly heard and understood at the receiving end of his line, but in his specification he did describe accurately and with admirable clearness his process, that is to say, the exact electrical condition that must be created to accomplish his purpose, and he also described, with sufficient precision to enable one of ordinary skill in such matters to make it, a form of apparatus which, if used in the way pointed out, would produce the required effect, receive the words, and carry them to and deliver them at the appointed place. The particular instrument which he had, and which he used in his experiments, did not, under the circumstances in which it was tried, reproduce the words spoken, so that they could be clearly understood, but the proof is abundant and of the most convincing character, that other instruments, carefully constructed and made exactly in accordance with the specification, without any additions whatever, have operated and will operate successfully. A good mechanic of proper skill in matters of the kind can take the patent and, by following the specification strictly, can, without more, construct an apparatus which, when used in the way pointed out, will do all that it is claimed the method or process will do

"The law does not require that a discoverer or inventor, in order to get a patent for a process, must have succeeded in bringing his art to the highest degree of perfection. It is enough if he describes his method with sufficient clearness and precision to enable those skilled in the matter to understand what the process is, and if he points out some practicable way of putting it into operation." *The Telephone Cases*, 126 U.S. 1, 535-536 (1888).10

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When we apply the reasoning of *The Telephone Cases* to the facts of the case before us today, it is evident that Pfaff could have obtained a patent on his novel socket when he accepted the purchase order from Texas Instruments for 30,100 units. At that time he provided the manufacturer with a description and drawings that had "sufficient clearness and precision to enable those skilled in the matter" to produce the device. The parties agree that the sockets manufactured to fill that order embody Pfaff's conception as set forth in claims 1, 6, 7, and 10 of the '377 patent. We can find no basis in the text of Section 102(b) or in the facts of this case for concluding that Pfaff's invention was not "on sale" within the meaning of the statute until after it had been reduced to practice.

III

Pfaff nevertheless argues that longstanding precedent, buttressed by the strong interest in providing inventors with a clear standard identifying the onset of the 1-year period, justifies a special interpretation of the word "invention" as used in Section 102(b). We are persuaded that this nontextual argument should be rejected.

As we have often explained, most recently in *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 151 [9 USPQ2d 1847] (1989), the patent system represents a carefully crafted bargain that encourages both the creation and the public disclosure of new and useful advances in technology, in return for an exclusive monopoly for a limited period of time. The balance between the interest in motivating innovation and enlightenment by rewarding invention with patent protection on the one hand, and the interest in avoiding monopolies that unnecessarily stifle competition on the other, has been a feature of the federal patent laws since their inception. As this Court explained in 1871:

"Letters patent are not to be regarded as monopolies . . . but as public franchises granted to the inventors of new and useful improvements for the purpose of securing to them, as such inventors, for the limited term therein mentioned, the exclusive right and liberty to make and use and vend to others to be used their own inventions, as tending to promote the progress of science and the useful arts, and as matter of compensation to the inventors for their labor, toil, and expense in making the inventions, and reducing the same to practice for the public benefit, as contemplated by the Constitution and sanctioned by the laws of Congress." *Seymour v. Osborne*, 11 Wall. 516, 533-534.

Consistent with these ends, Section 102 of the Patent Act serves as a limiting provision, both excluding ideas that are in the public domain from patent protection and confining the duration of the monopoly to the statutory term. See, e.g., *Frantz Mfg. Co. v. Phenix Mfg. Co.*, 457 F.2d 314, 320 [173 USPQ 266] (CA7 1972).

We originally held that an inventor loses his right to a patent if he puts his invention into public use before filing a patent application. "His voluntary act or acquiescence in the public sale and use is an abandonment of his right" *Pennock v. Dialogue*, 2 Pet. 1, 24 (1829) (Story, J.). A similar reluctance to allow an inventor to remove existing knowledge from public use undergirds the on-sale bar.

Nevertheless, an inventor who seeks to perfect his discovery may conduct extensive testing without losing his right to obtain a patent for his invention—even if such testing occurs in the public eye. The law has long recognized the distinction between inventions put to experimental use and products sold commercially. In 1878, we explained why patentability may turn on an inventor's use of his product.

"It is sometimes said that an inventor acquires an undue advantage over the public by delaying to take out a patent, inasmuch as he thereby preserves the monopoly to himself for a longer period than is allowed by the policy of the law; but this cannot be said with justice when the delay is occasioned by a *bona fide* effort to bring his invention to perfection, or to ascertain whether it will answer the purpose intended. His monopoly only continues for the allotted period, in any event; and it is the interest of the public, as well as himself, that the invention should be perfect and properly tested, before a patent is granted for it. *Any attempt to use it for a profit*,

and not by way of experiment, for a longer period than two years before the application, would deprive the inventor of his right to a patent ." *Elizabeth v. Pavement Co.* , 97 U.S. 126, 137 (emphasis added).

The patent laws therefore seek both to protect the public's right to retain knowledge already in the public domain and the inventor's right to control whether and when he may patent his invention. The Patent Act of 1836, 5 Stat. 117, was the first statute that expressly included an on-sale bar to the issuance of a patent. Like the earlier holding in *Pennock* , that provision precluded patentability if the invention had been placed on sale at any time before the patent application was filed. In 1839, Congress ameliorated that requirement by enacting a 2-year grace period in which the inventor could file an application. 5 Stat. 353.

In *Andrews v. Hovey*, 123 U.S. 267, 274 (1887), we noted that the purpose of that amendment was "to fix a period of limitation which should be certain"; it required the inventor to make sure that a patent application was filed "within two years from the completion of his invention," *ibid.* In 1939, Congress reduced the grace period from two years to one year. 53 Stat. 1212.

Petitioner correctly argues that these provisions identify an interest in providing inventors with a definite standard for determining when a patent application must be filed. A rule that makes the timeliness of an application depend on the date when an invention is "substantially complete" seriously undermines the interest in certainty. 11 Moreover, such a rule finds no support in the text of the statute. Thus, petitioner's argument calls into question the standard applied by the Court of Appeals, but it does not persuade us that it is necessary to engraft a reduction to practice element into the meaning of the term "invention" as used in Section 102(b).

The word "invention" must refer to a concept that is complete, rather than merely one that is "substantially complete." It is true that reduction to practice ordinarily provides the best evidence that an invention is complete. But just because reduction to practice is sufficient evidence of completion, it does not follow that proof of reduction to practice is necessary in every case. Indeed, both the facts of the *Telephone Cases* and the facts of this case demonstrate that one can prove that an invention is complete and ready for patenting before it has actually been reduced to practice.¹²

[1] We conclude, therefore, that the on-sale bar applies when two conditions are satisfied before the critical date. First, the product must be the subject of a commercial offer for sale. An inventor can both understand and control the timing of the first commercial marketing of his invention. The experimental use doctrine, for example, has not generated concerns about indefiniteness, 13 and we perceive no reason why unmanageable

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uncertainty should attend a rule that measures the application of the on-sale bar of Section 102(b) against the date when an invention that is ready for patenting is first marketed commercially. In this case the acceptance of the purchase order prior to April 8, 1981, makes it clear that such an offer had been made, and there is no question that the sale was commercial rather than experimental in character.

Second, the invention must be ready for patenting. That condition may be satisfied in at least two ways: by proof of reduction to practice before the critical date; or by proof that prior to the critical date the inventor had prepared drawings or other descriptions of the invention that were sufficiently specific to enable a person skilled in the art to practice the invention. 14 In this case the second condition of the on-sale bar is satisfied because the drawings Pfaff sent to the manufacturer before the critical date fully disclosed the invention.

The evidence in this case thus fulfills the two essential conditions of the on-sale bar. As succinctly stated by Learned Hand:

" [I]t is a condition upon an inventor's right to a patent that he shall not exploit his discovery competitively after it is ready for patenting; he must content himself with either secrecy, or legal monopoly." *Metallizing Engineering Co. v. Kenyon Bearing & Auto Parts Co.*, 153 F.2d 516, 520 [68 USPQ 54] (CA2 1946).

[2] The judgment of the Court of Appeals finds support not only in the text of the statute but also in the basic

policies underlying the statutory scheme, including Section 102(b). When Pfaff accepted the purchase order for his new sockets prior to April 8, 1981, his invention was ready for patenting. The fact that the manufacturer was able to produce the socket using his detailed drawings and specifications demonstrates this fact. Furthermore, those sockets contained all the elements of the invention claimed in the '377 patent. Therefore, Pfaff's '377 patent is invalid because the invention had been on sale for more than one year in this country before he filed his patent application. Accordingly, the judgment of the Court of Appeals is affirmed.

It is so ordered.

Footnotes

Footnote 1. "A person shall be entitled to a patent unless--

..... "(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States, or" 35 U.S.C. Section 102.

Footnote 2. "A process is reduced to practice when it is successfully performed. A machine is reduced to practice when it is assembled adjusted and used. A manufacture is reduced to practice when it is completely manufactured. A composition of matter is reduced to practice when it is completely composed." *Corona Cord Tire Co. v. Dovan Chemical Corp.*, 276 U.S. 358, 383 (1928).

Footnote 3. At his deposition, respondent's counsel engaged in the following colloquy with Pfaff:

"Q. Now, at this time [late 1980 or early 1981] did we [sic] have any prototypes developed or anything of that nature, working embodiment?

"A. No.

"Q. It was in a drawing. Is that correct?

"A. Strictly in a drawing. Went from the drawing to the hard tooling.

That's the way I do my business.

"Q. 'Boom-boom'?

"A. You got it.

"Q. You are satisfied, obviously, when you come up with some drawings that it is going to go -- 'it works'?

"A. I know what I'm doing, yes, most of the time." App. 96-97.

Footnote 4. Initial sales of the patented device were:

1981	\$350,000
1982	\$937,000
1983	\$2,800,000
1984	\$3,430,000

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Footnote 5. *Pfaff v. Wells Electronics, Inc.*, 9 USPQ2d 1366 (ND Ind. 1988). The court found that the Wells device did not literally infringe on Pfaff's '377 patent based on the physical location of the sockets' conductive pins.

Footnote 6. Initially the District Court entered summary judgment in favor of respondent, but the Court of Appeals reversed and remanded for trial because issues of fact were in dispute. See 5 F.3d 514 [28 USPQ2d 1119] (CA Fed. 1993).

Footnote 7. Title 35 U.S.C. Section 103 provides: "A patent may not be obtained though the invention is not identically disclosed or described . . . if the differences between the subject matter sought to be patented and the

prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains."

Footnote 8. Title 35 Section 100, "Definitions," states,

"When used in this title unless the context otherwise indicates--

"(a) The term 'invention' means invention or discovery. . . ."

Footnote 9. Section 101, "Inventions patentable," provides, "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title."

Footnote 10. This Court has also held a patent invalid because the invention had previously been disclosed in a prior patent application, although that application did not claim the invention and the first invention apparently had not been reduced to practice. *Alexander Milburn Co. v. Davis-Bournonville Co.*, 270 U.S. 390, 401-402 (1926).

Footnote 11. The Federal Circuit has developed a multifactor, "totality of the circumstances" test to determine the trigger for the on-sale bar. See, e.g., *Micro Chemical, Inc. v. Great Plains Chemical Co.*, 103 F.3d 1538, 1544 [41 USPQ2d 1238] (1997) (stating that, in determining whether an invention is on sale for purposes of 102(b), "all of the circumstances surrounding the sale or offer to sell, including the stage of development of the invention and the nature of the invention, must be considered and weighed against the policies underlying section 102(b)"); see also *UMC Electronics Co. v. United States*, 816 F.2d 647, 656 [2 USPQ2d 1465] (1987) (stating the on-sale bar "does not lend itself to formulation into a set of precise requirements"). As the Federal Circuit itself has noted, this test "has been criticized as unnecessarily vague." *Seal-Flex, Inc. v. Athletic Track & Court Construction*, 98 F.3d 1318, 1323, n.2 [40 USPQ2d 1450] (1996).

Footnote 12. Several of this Court's early decisions stating that an invention is not complete until it has been reduced to practice are best understood as indicating that the invention's reduction to practice demonstrated that the concept was no longer in an experimental phase. See, e.g., *Seymour v. Osborne*, 11 Wall. 516, 552 (1871) ("Crude and imperfect experiments are not sufficient to confer a right to a patent; but in order to constitute an invention, the party must have proceeded so far as to have reduced his idea to practice, and embodied it in some distinct form"); *Clark Thread Co. v. Willimantic Linen Co.*, 140 U.S. 481, 489 (1891) (describing how inventor continued to alter his thread winding machine until July 1858, when "he put it in visible form in the shape of a machine. . . . It is evident that the invention was not completed until the construction of the machine"); *Corona Cord Tire Co. v. Dovan Chemical Corp.*, 276 U.S., at 382-383 (stating that an invention did not need to be subsequently commercialized to constitute prior art after the inventor had finished his experimentation. "It was the fact that it would work with great activity as an accelerator that was the discovery, and that was all, and the necessary reduction to use is shown by instances making clear that it did so work, and was a completed discovery").

Footnote 13. See, e.g., Rooklidge & Jensen, Common Sense, Simplicity and Experimental Use Negation of the Public Use and On Sale Bars to Patentability, 29 John Marshall L. Rev. 1, 29 (1995) (stating that "whether a particular activity is experimental is often clear").

Footnote 14. The Solicitor General has argued that the rule governing on-sale bar should be phrased somewhat differently. In his opinion, "if the sale or offer in question embodies the invention for which a patent is later sought, a sale or offer to sell that is primarily for commercial purposes and that occurs more than one year before the application renders the invention unpatentable. *Seal-Flex, Inc. v. Athletic Track and Court Constr.*, 98 F.3d 1318, 1325 [40 USPQ2d 1450] (Fed. Cir. 1996) (Bryson, J., concurring in part and concurring in the result)." It is true that evidence satisfying this test might be sufficient to prove that the invention was ready for patenting at the time of the sale if it is clear that no aspect of the invention was developed after the critical date. However, the possibility of additional development after the offer for sale in these circumstances counsels against adoption of the rule proposed by the Solicitor General.

- End of Case -

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